



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/971,708	10/09/2001	Youmin Shu	16U 102 R1	4218
23599	7590	01/05/2004	EXAMINER	
MILLEN, WHITE, ZELANO & BRANIGAN, P.C. 2200 CLARENDON BLVD. SUITE 1400 ARLINGTON, VA 22201			ANDRES, JANET L	
		ART UNIT		PAPER NUMBER
		1646		

DATE MAILED: 01/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

SM

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	09/971,708	SHU ET AL.	
	Examiner	Art Unit	
	Janet L. Andres	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1) Responsive to communication(s) filed on 21 October 2003.

2a) This action is **FINAL**.      2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4) Claim(s) 1,3-7,9-20 and 22-24 is/are pending in the application.

4a) Of the above claim(s) 1,3-7 and 9-20 is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 22-24 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. §§ 119 and 120**

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All    b) Some \*    c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

13) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) The translation of the foreign language provisional application has been received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

**Attachment(s)**

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.

4) Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_.

5) Notice of Informal Patent Application (PTO-152)

6) Other: \_\_\_\_\_

## **RESPONSE TO AMENDMENT**

1. Applicant's amendment filed 21 October 2003 is acknowledged. Claims 1, 3-7, 9-20, and 22-24 are pending in this application. Claims 1, 3-7, and 9-20 are withdrawn from consideration as being drawn to a non-elected invention.

### ***Claim Rejections/Objections Maintained***

2. The objection to the specification is maintained for reasons of record in the office action of 25 July 2003. The embedded hyperlink is still present on p. 4, lines 24-25.

3. The rejection of claims 22-24 under 35 U.S.C. 101 as lacking either a specific and substantial asserted utility or a well-established utility is maintained for reasons of record in the office action of 25 July 2003.

Applicant states that the claimed invention is a tyrosine kinase and that it can be used to label substrates for use in assays. Applicant further argues that enzyme activity is adequate to satisfy the utility requirements, citing example 5 of the utility guidelines training materials.

Applicant additionally cites Cross v. Iizuka and MPEP 2107.01. Applicant further argues that the enzyme can be used as a pancreas marker and that the fact that it is found in other cell types does not detract from this utility. Applicant additionally argues that it can be used to detect metastatic pancreatic cells.

Applicant's arguments have been fully considered but have not been found to be persuasive.

---

The claims are drawn to a method of detection of KSE132, which is known in the art as EphA6, in pancreatic cells. As stated in the previous office action, both the polypeptide and the method of use lack utility. That the polypeptide is an enzyme does not endow it with a utility.

There is no particular function associated with EphA6; thus, labeling substrates for use in assays would be useful only to investigate the function of the protein itself. The hypothetical enzyme referred to in example 5 of the guidelines is a “well-known tyrosine kinase” and the example further assumes that the substrates are well known. There are, however, many different tyrosine kinases with many different substrates and many different functions; merely identifying a protein as having this activity does not provide any information as to what it does or how it could be used. Similarly, *Cross v. Iizuka* deals with inhibitors of thromboxane synthetase, a well-known enzyme with a particular known function. MPEP §2107.01 discusses utility guidelines in general and cites *Cross v. Iizuka*; none of the cited references indicate that enzymatic activity alone, absent any known use for that activity, is sufficient to endow the protein that possesses it with a utility. Thus, there is no specific and substantial utility associated with the protein or with its detection in a particular cell type. The function of the protein is not known, it is not known to be associated with any disease, and thus there is no benefit to be gained from detecting its presence. Use of the protein as a marker for pancreatic cells is not a specific utility; it could apply to any protein and does not depend on the particular properties of KSE132/EphA6. Neither the specification nor the prior art identifies any association with any disease; it is not, for example, known to be differentially expressed in metastatic pancreatic cells. Thus its use in identifying such cells would simply be to identify cells of pancreatic origin and, as stated above, is not a specific utility, because it does not depend on any properties of the protein itself.

---

4. The rejection of claims 22-24 under 35 U.S.C. 112, first paragraph, as lacking enablement because the invention lacks utility, is maintained for reasons of record in the office action of 25 July 2003.

Applicant argues as set forth above. Since, for the reasons stated above, Applicant's arguments with respect to utility are not found to be persuasive, the invention lacks utility and one skilled in the art would not know how to use it.

NO CLAIM IS ALLOWED.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet Andres, Ph.D., whose telephone number is (703) 305-0557. The examiner can normally be reached on Monday through Friday from 8:00 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, Ph.D., can be reached at (703) 308-6564. The fax phone number for this group is (703) 872-9306 or (703) 872-9307 for after final communications.

Art Unit: 1646

Communications via internet mail regarding this application, other than those under U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [\[yvonne.eyler@uspto.gov\]](mailto:yvonne.eyler@uspto.gov).

All Internet email communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark Office on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Janet Andres, Ph.D.  
December 29, 2003



Janet Andres  
PATENT EXAMINER